



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,147	04/08/2004	Linda Valeric Thomas	14966.0004	6681

7590 02/27/2007
STEPTOE & JOHNSON LLP
Attn: Docket Administrator - Box USPTO
1330 Connecticut Avenue, NW
Washington, DC 20036

EXAMINER

PADEN, CAROLYN A

ART UNIT	PAPER NUMBER
----------	--------------

1761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/820,147

Applicant(s)

THOMAS ET AL.

Examiner

Carolyn A. Paden

Art Unit

1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 17-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 33, 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-20-06 has been entered.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over 21 CFR 172.156 in view of Morgan for reasons of record.

CFR describes where natamycin is permitted in foods as an antimycotic agent. The passage restricts the use of natamycin to the surface of cheese. It is very well known in the art that fat and wax are typically used to coat quality cheese products, such as Edam cheese, in order to protect the cheese from the ordinary environment. Given the

approved use of natamycin in cheese, it would have been obvious to look for a fat or wax coating that could be used as a vehicle for natamycin.

Thus it would have been obvious to look to Morgan, who teaches powdered microcapsules for use in foods. Morgan teaches making microcapsules from oil in water emulsion by spray drying the emulsion that may contain antimycotic agents. Oil and wax are contemplated as shells from this process. The cores of the microcapsules are aqueous and may contain antimycotic agents (column 5, last line). It would have been obvious to one of ordinary skill in the art to utilize natamycin in the microcapsule of Morgan as one of a host of permitted anti-mycotic agents for use in cheese coating. It is appreciated that the dosage levels of claims 33 and 34 are not mentioned but one of ordinary skill in the art would be able to adjust the dosage in Morgan according to the amount of microencapsulated powder desired in the fat or wax coating used to coat the cheese.

Applicant argues that the references do not provide for the dosage level set forth in the claims. But given the specific guidelines set forth by the FDA, one of ordinary skill in the food art would have been able to determine dosage levels needed to fall within the required FDA dosage limits. Applicant argues that the reference does not provide for a

physiologically acceptable shell. This has been considered but is not persuasive because all of the ingredients are for use in foods. So one of ordinary skill in the art would have expected that these ingredients are physiologically acceptable. Applicant argues that there is no suggestion in the primary reference to use the substances of the secondary references. But given the broad guidelines provided by the FDA, it would have been obvious to the typical food technologist to look to fat and wax sources, such as provided for in Morgan, as vehicles for antimycotic agents because the fat and wax cheese coatings are for the surface treatment of cheese.

Applicant argues that the references does not have the specific properties that are set forth in the claims, such as protecting properties and releasing properties. But oil and wax are known to protect cheese from the elements. There is no indication in the art that fat and wax would not be an adequate shell fro natamycin.

Claims 1, 6, 9-16, 33 & 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thies (Micro encapsulation) in view of Stark (Natamycin).

Thies discloses all of the ways in which food, pharmaceuticals and biotechnological ingredients may be microencapsulated. Table 1 shows

the shell materials. The abstract shows the range of ingredients for use in microcapsules. The claims appear to differ from Thies in the inclusion of natamycin as one of the many applications for microcapsules. Stark teaches Natamycin. The physical properties of natamycin are shown on page 180. It would have been obvious to one of ordinary skill in the art to supplement any or all of the many biotechnological applications of microcapsules with natamycin in order to reduce the extent of fungus and mold growth in the product. It is appreciated that the particular amount of natamycin set forth in claims 14-16 is not shown but to prepare a super concentrated solution of natamycin for dilution would have been an obvious way to simplify the preparation of a usable amount of compound. Further it would have been obvious to any responsible businessman to set forth dosage levels for the safe use of the natamycin product. Guidance for the dosage levels is provided by country at pages 192-193 of Stark.

Applicant argues that there is no suggestion in Thies to select natamycin dosages within physiologically acceptable shell. But Thies provides for the concept of encapsulation of anti-mycotics in general. No unobvious or unexpected result is seen from the selection of natamycin specifically. Thies, in Table 1, provides a list of shell materials for the micro

encapsulation of foods and pharmaceuticals. Given the utility of the shell materials in foods and oral pharmaceuticals, one of ordinary skill in the art would expect these shell materials to be physiologically acceptable materials.

Applicant argues that the references do not show that the shell for the natamycin protects the natamycin from degradation. This argument has been considered but is not persuasive. But pages 2-4 of Thies clearly show the preservative advantages of microencapsulation of ingredients. One of ordinary skill in the art would expect these advantages to apply to natamycin as well as pharmaceuticals, biomedical ingredients and foods.

No claim is allowed.

This is a Continued Examination of applicant's earlier Application No. 10/820,147. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn A Paden whose telephone number is (571) 272-1403. The examiner can normally be reached on Monday to Friday from 7 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached on (571) 272-1398 or by dialing 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CAROLYN PADEN 2-16-07
PRIMARY EXAMINER 1761